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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EDWARD J. LYNCH DUANE MORRIS LLP ONE MARKET SPEAR TOWER, SUITE 2000 SAN FRANCISCO, CA 94105			EXAMINER SMITH, FANGEMONIQUE A	
			ART UNIT 3736	PAPER NUMBER
			MAIL DATE 08/27/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/642,406

Applicant(s)

QUICK ET AL.

Examiner

Fangemonique Smith

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 11 May 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,7-10,15,16,19,21,71,73-85,87 and 89-95 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,7-10,15,16,19,21,71,73-85,87 and 89-95 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application
- ☐ Other: _____.

DETAILED ACTION

1. This Office Action is responsive to the Response to the amendment filed on May 11, 2007. The Examiner acknowledges the cancellation of claims 2-6, 11-14, 17-18, 20, 22-70, 72, 86, 88 and 96; and the amendment of claims 1, 8, 15, 19, 71, 76, 85, 89 and 90. Claims 1, 7-10, 15, 16, 19, 21, 71, 73-85, 87 and 89-95 are pending.

Claim Objections

2. Claim 1 is objected to because of the following informalities:
 - a. At lines 13 and 14, it is suggested to modify the limitation "an inner lumen extending therein to an in fluid communication with" to read -- an inner lumen extending therein and in fluid communication with --.Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
4. Claims 85, 87 and 89-95 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
5. Claim 85 recites the limitation "the outer cutting edge" in line 10. It is unclear whether this limitation intends to refer to the at least one outer tissue cutting edge of the tissue cutting member, or if the limitation intends to refer to the tissue cutting edge of the outer tubular

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member, rendering the claim indefinite. Upon rejection of claim 85, any claim depending from claim 85 is also rejected.

6. Claim 88 recites the limitation "the opposed tissue cutting edges". There is no prior mention of opposed tissue cutting edges in claim 88 or in any claim from which claim 88 depends. Therefore, there is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1, 7 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miller et al. (U.S. Patent Number 6,758,824) in view of Levin (U.S. Patent Number 5,578,030).

In regard to claim 1, 7 and 19, Miller et al. disclose a tissue biopsy device (10) for accessing and collecting a tissue specimen from a target site within a patient. The biopsy device comprises an elongated probe member (15), which has a proximal end configured to be secured to a drive and an inner lumen (27) extending along a longitudinal axis. Miller et al. describe the probe further having a penetrating distal tip (16) and an aperture (25) proximal to the penetrating distal tip configured to receive tissue from the target site. The Miller et al. device further includes an elongated tissue cutting member (17), which is disposed within the elongated probe member (15), which has at least one tissue cutting edge (35, 36). The at least one cutting edge creates an

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angle with respect to the longitudinal axis less than 90 degrees (Fig. 5) and engages a tissue cutting edge (35) of the tissue cutting member.

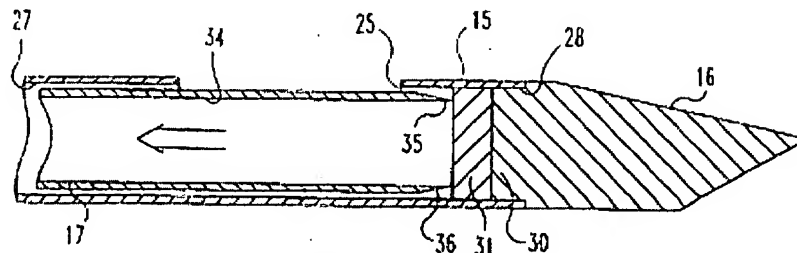


Fig. 5

The tissue cutting member (17) has an inner lumen (34), which is configured to be operably connected to at least one drive unit (22). The inner lumen (34) of the tissue cutting member (17) is further configured to access a vacuum source to transport a tissue specimen through the inner lumen (34) to a tissue collector (55) in fluid communication with the inner lumen. The aperture (25) of the probe (15) has at least one longitudinally oriented tissue cutting edge, which engages a tissue cutting edge (35) of the beveled tip of the tissue cutting member (17). The tissue cutting edge (35) of the tissue cutting member (17) has a tissue cutting angle over a substantial part of its length with respect to the tissue cutting edge of the aperture of about 30 to about 75 degrees (col. 19, lines 15-47). Miller et al. disclose a tissue biopsy device for accessing and collecting a tissue specimen from a target site within a patient. Miller et al. disclose the inner lumen of the tissue cutting member (17) is configured to access a vacuum source (150) to transport a cut tissue specimen to a tissue collection trap (55) in fluid communication with the inner lumen of the tissue cutting member. The aperture (25) of the probe (15) has at least one longitudinally distally oriented tissue cutting edge, which engages a tissue cutting edge (35) of the beveled needle-like

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tip of the tissue cutting member (17). The tissue cutting edge (35) of the tissue cutting member (17) has a tissue cutting angle over a substantial part of its length with respect to the tissue cutting edge of the aperture of about 30 to about 75 degrees (col. 19, lines 15-47). Miller et al. disclose the probe comprising an outer member (75), which has a proximal tubular portion (15) configured to be releasably secured to a drive housing (70) and an inner lumen (17) extending therein. A tissue penetrating distal tip (16) is disclosed by Miller et al. The device has an open section (25) proximal to the penetrating distal tip (16) and a supporting strut (30) extending from the penetrating distal tip to the proximal tubular portion (15). Miller et al. disclose an elongated tissue cutting member (17), which is formed at least in part of a tubular member, slidably disposed within the inner lumen of the tissue accessing cannula (43). The tissue cutting member has a tissue cutting edge (35), which has an inner lumen (34) configured to receive a tissue specimen cut by the tissue cutting member. The tissue cutting member (17) is further connected to a drive unit (20) to move the tissue cutting member (17) within the inner lumen of the tissue accessing cannula. The cutting edge (35) of the device is parallel to a longitudinal axis of the tissue cutting member (17) and the tissue cutting member moves longitudinally in a reciprocating motion about the longitudinal axis (col. 8, lines 1-45). The reciprocating motor is capable of moving the tissue cutting member in a reciprocal longitudinal movement of between about 0.01 inch and about 0.2 inch. The tissue accessing cannula (43) has a distal end (28) seated against a proximal surface of the tissue penetrating distal tip (16) of the outer member. The tissue accessing cannula is operably secured to a drive unit (20) in the drive housing (70) to rotate the tissue receiving cannula (50). In addition, Miller et al. disclose an elongated tissue cutting member (17), which is formed at least in part of a tubular member, slidably disposed within the

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inner lumen of the tissue accessing cannula (43). The tissue cutting member has a tissue cutting edge (35), which has an inner lumen (34) configured to receive a tissue specimen cut by the tissue cutting member (17). The tissue cutting member (17) is rotatably disposed within the inner lumen of the tissue accessing cannula (34) with a longitudinal axis and a longitudinal tissue cutting edge oriented at an angle with respect to the longitudinal axis. Miller et al. further disclose the tissue cutting member having a non-cutting surface, which defines a tissue receiving aperture along with the tissue cutting edge parallel to the tissue cutting member. The cutting edge of the tissue cutting member further includes a leading distal cutting edge portion and an opposing trailing proximal cutting edge portion. Although Miller et al. disclose a tissue cutting edge having an angle less than 90 degrees with respect to the longitudinal axis, the Miller et al. cutting edge is inside which do not engage the outer tubular member as described by applicant. Levin discloses a biopsy device, which has a sharp cutting edge (38) which engages an outer tubular member of the device. The cutting edge is longitudinally arranged and allows a specimen to be collected into the specimen holding recess. It would have been obvious to one having ordinary skill in the art at the time the Applicants' invention was made to modify a tissue biopsy device for accessing and collecting a tissue specimen from a target site, similar to that disclosed by Miller et al., to include a tissue cutting member with a edge which engages an outer tubular member of the device, similar to that disclosed by Levin, to provide another way to sever tissue from the target site and separate the severed tissue sample within the probe while maintaining the functionality of the device.

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9. Claims 8-10, 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miller et al. (U.S Patent Number 6,758,824) in view of Levin (U.S. Patent Number 5,578,030) and in further view of Ouchi (U.S Patent Number 6,514,215).

In regard to claims 8-10, 15 and 16, the combined references of Miller et al. and Levin disclose the features of the Applicant's invention as described above. The combined references do not disclose a third concentrically disposed cannula with an arcuate wall section slidably disposed about the tissue cutting member. Ouchi discloses a tissue collecting instrument having a tissue cutting member disposed within a probe member (230) and a rotatable tissue accessing cannula (220) concentrically about the tissue cutting member (210). The tissue cutting member has an arcuate wall section. It would have been obvious to one having ordinary skill in the art at the time the Applicants' invention was made to modify a tissue biopsy device for accessing and collecting a tissue specimen from a target site, similar to that disclosed by the combined references of Miller et al. and Levin, to include a third concentrically disposed cannula and a tissue cutting member with an arcuate wall section, similar to that disclosed by Ouchi, to sever tissue from the target site and separate the severed tissue sample within the probe while maintaining the functionality of the device.

10. Claims 21, 71, 73, 74, 83, and 84 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miller et al. (U.S Patent Number 6,758,824) in view of Mauze et al. (U.S. Patent Number 6,176,865).

In regard to claims 21, 71, 73, 74, 83 and 84, Miller et al. disclose a tissue biopsy device (10) for accessing and collecting a tissue specimen from a target site within a patient. The biopsy device comprises an elongated tubular member (15), which has a proximal end configured to be secured

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to a drive and an inner lumen (27) extending along a longitudinal axis. Miller et al. describe the probe further having a penetrating distal tip (16) and an aperture (25) proximal to the penetrating distal tip configured to receive tissue from the target site. The Miller et al. device further includes an elongated tissue cutting member (17) with a beveled distal tissue cutting tip, which is disposed within the elongated probe member (15), and has at least one tissue cutting edge (35, 36). The at least one cutting edge creates an angle with respect to the longitudinal axis less than 90 degrees (Fig. 5) and engages a tissue cutting edge (35) of the tissue cutting member. Although Miller et al. disclose the features of the Applicant's invention as described above, Miller et al. do not disclose the outer tissue cutting edge of the tissue cutting tip engaging the tissue cutting edge of the outer tubular member. Mauze et al. disclose a method and apparatus for incising which includes a multi-shaft apparatus for incising a substrate of body tissue. The multi-shaft apparatus has a cutting edge on the outer tubular member, which engages with the cutting member of the inner cutting element. The distal tip of the device has opposed tissue cutting edges. It would have been obvious to one having ordinary skill in the art at the time the Applicants' invention was made to modify a tissue biopsy device for accessing and collecting a tissue specimen from a target site, similar to that disclosed by Miller et al., to include a tissue cutting member with a edge which engages a cutting edge of the outer tubular member of the device, similar to that disclosed by Levin, to provide a less painful way to sever tissue from the target site and separate the severed tissue sample within the probe while maintaining the functionality of the device.

11. Claims 75-82, 85, 87 and 89-95 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miller et al. (U.S Patent Number 6,758,824) in view of Mauze et al. (U.S. Patent Number 6,176,865) and in further view of Clement (U.S Patent Number 5,335,671).

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In regard to claims 75-82, 85, 87 and 89-95, the combined references of Miller et al. and Levin disclose the features of the Applicant's invention as described above. The combined references do not disclose a longitudinally oriented slot in a wall of the tubular member having a distal end that opens to the tissue receiving opening in the distal tip of the device. Clement discloses a tissue removal assembly having a tissue cutting member, which uses a moveable cutter cooperating with a cutting surface on a cannula positioned at a target site. The tissue removal assembly further includes longitudinally oriented slots on a wall of the tubular member to ensure constant fluid communication between the cannula passageway and the tubular member. It would have been obvious to one having ordinary skill in the art at the time the Applicants' invention was made to modify a tissue biopsy device for accessing and collecting a tissue specimen from a target site, similar to that disclosed by the combined references of Miller et al. and Levin, to include a slotted wall section of the tubular member, similar to that disclosed by Clement, to maintain the channels in fluid communication with one another for aspiration purposes.

Response to Arguments

12. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., at least one outer tissue cutting edge configured to engage the tissue cutting edge of the outer tubular member) are not recited in the rejected claims 1, 7-10, 15, 16 and 19. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

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13. Applicant's arguments with respect to claims 21, 71, 73-85, 87 and 89-95 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fangemonique Smith whose telephone number is 571-272-8160. The examiner can normally be reached on Mon - Fri 8am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

FS


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